

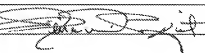
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

89000.3013NP

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Signature



Typed or printed name Selena Whitaker-Paquet

Application Number

10/798,623

Filed

10 March 2004

First Named Inventor

WULFMAN, Edward I. et al.

Art Unit

3731

Examiner

WEBB, Sarah K.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the



applicant/inventor.



assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/98)



attorney or agent of record.

Registration number 31,881

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



Signature

Ann W. Speckman

Typed or printed name

206-382-1191

Telephone number

27 October 2011

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below".



*Total of 3 forms are submitted.

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Date of Submission: October 27, 2011


Selena Whitaker-Paquet

Attorney Docket No. 89000.3013NP
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re **Edward I. WULFMAN and Casey TORRANCE**

Group Art Unit: 3731

Application No. : 10/798,623
Filed : March 10, 2004
For : **LIQUID SEAL ASSEMBLY FOR A ROTATING TORQUE TUBE**
Examiner : Sarah K. Webb

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP: AF
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P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

Applicants respectfully request a review of the legal and factual bases of the outstanding rejections in the above-identified patent application. Pursuant to the guidelines set forth in the Official Gazette Notice of July 12, 2005 for the Pre-Appeal Brief Conference Pilot Program, favorable reconsideration of the subject application is respectfully requested in view of the following remarks. A Notice of Appeal is being submitted concurrently with this submission.

The present application has undergone a lengthy prosecution. In a final Office Action mailed on February 4, 2010, the claims pending at that time were rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent No. 5,217,474 to Zacca et al. ("Zacca") in view of US Patent 5,490,859 to Mische et al. ("Mische"), either alone or further in view of US Patent 5,938,670 to Keith et al., US Patent No. 6,258,052 to Milo ("Milo") and/or US Patent 4,976,720 to Machold et al. In response, applicants filed an Appeal Brief on August 4, 2010, pointing out the Examiner's misunderstanding of the Zacca reference in particular. Prosecution was subsequently re-opened.

After further prosecution, including filing a Request for Continuing Examination, a non-final Office Action was mailed on October 28, 2010, in which claims 2-5, 10, 17, 19, 20, 22-24, 26 and 27 were rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 6,080,170 to Nash et al. ("Nash"). Following a telephone interview with the Examiner, the applicants submitted an Amendment and Reply amending independent claims 19 and 20 to more clearly define the claimed device. A final Office Action was mailed on July 28, 2011, finally rejecting claims 2-5, 10, 17, 19, 20 22-24 and 26-28 under 35 U.S.C. §103(a) as being unpatentable over Nash in view of Zacca. The final Office Action included a rejection of claim 28 under 35 U.S.C. §112, second paragraph, as being indefinite due to a minor error in the claim language. This error was corrected in an Amendment After Final mailed on October 11, 2011.

The present Notice of Appeal and Pre-Appeal Brief Request for Review relate to the final rejections of independent claims 19 and 20 under 35 U.S.C. §103(a) as stated in the final Office Action of July 28, 2011. Applicants submit that there are clear errors and omissions in the outstanding final rejection and that independent claims 19 and 20 are in allowable form.

The present application discloses and claims an aspirating catheter device having a liquid seal assembly that provides an air-tight, substantially friction-free seal around a rotatable torque tube (e.g., a high speed rotational driveshaft) operating in proximity to an area of high vacuum. Conventional sealing mechanisms, such as O-rings, bushings and bearings, which are typically used to provide a liquid seal for a drive shaft, are prone to leakage and frictional heating as drive shafts of interventional catheters rotate, particularly at high rotational rates, during operation of the devices. The claimed device overcomes this problem by providing a stationary, liquid-filled liner surrounding the torque tube at the sealing site to provide a flood space that functions as an air-tight, substantially friction-free seal around the rotating torque tube. The liner is surrounded by a catheter and liquid exits the liner distally at an intersect site within an aspiration lumen formed by the surrounding catheter. The rotatable torque tube, the sealing assembly including the liner with its flood space, and the catheter enclosing the liner, all form part of the claimed aspirating catheter.

Specifically, independent claims 19 and 20 are drawn, in part, to devices including: a rotatable torque tube operably connected at a proximal end to a drive system for rotation and at a distal end to a working head; a liner that surrounds the torque tube and extends from a sealing site within the housing to terminate distally at an intersect area located proximal to the distal end

of the torque tube (*i.e.* proximal to the working head); a liquid flood space located between the liner and the torque tube; and a catheter that extends distally beyond the intersect area to enclose the torque tube and the liner, and forms an aspiration lumen between the catheter and the liner. Liquid infused into the flood space during operation of the device provides a sealing medium in the liquid seal assembly and exits the flood space at the intersect area. Claim 20 further recites that liquid exiting the flood space at the intersect area directly enters the aspiration lumen.

Nash discloses an atherectomy catheter in which a distal working head impacts occlusive material to open a lumen and infusate liquid is introduced through a catheter jacket (34) [referred to by the Examiner as liner (34)] proximal to and adjacent the working head. The infusate, and some blood and debris are withdrawn by aspiration through a guide catheter (24) positioned proximally of the infusion location. The infusion and aspiration flow rates are carefully controlled to create a differential flow adjacent the working head and promote collection of debris, with the infusate and blood, through aspiration proximal to the infusion site.

In the final Office Action mailed on July 28, 2011, the Examiner observes that Fig. 13 of Nash shows the proximal end of the torque tube (308 and 336) and drive system (322) and a sealing site (326) at the proximal end of the stationary liner (catheter jacket 34) within the housing. The Examiner alleges that although not specifically stated, the Nash apparatus performs the function of preventing air or other fluids from contacting movable catheter components in the proximal area of the torque tube. While the catheter jacket (34) is mounted at and extends away from a tapered portion of the housing at 326, the sealing site of Nash is within the housing and proximal to attachment of the catheter jacket (34) to the housing. In Nash's device, the seal is provided where the turbine rotor shaft (336) extends through sleeve bearing (344) and then an O-ring (346), which forms a fluid-tight seal. This is, in fact, the conventional sealing technique that applicants' claimed liquid seal assembly replaces. Moreover, while site (326) is the site at which the catheter jacket is sealed to the housing, it is not a sealing site enclosed by the housing (claim 20(b)(i)), and it does not create a liquid seal around the torque tube at that sealing site (claim 20(b)(c)). This is a clear error in the outstanding rejection.

The Examiner states that Nash fails to disclose a "liner" terminating proximal to the distal end of the torque tube and introduces Zacca for this teaching. As discussed on pages 14-15 of the Appeal Brief filed on August 4, 2010, the flexible catheter 14 of Zacca "protects the body's intervening vasculature from injury or trauma during rotation of the drive shaft" (*See*, col. 6, lines

4-8), and is also used to introduce cooling fluids around the drive shaft coil (*See*, col. 6, lines 32-34). The flexible catheter 14 of Zacca forms the outer-most surface of the device and is *not* equivalent or similar to the *liner* recited in applicants' pending independent claims 19 and 20, which is surrounded or enclosed by the claimed catheter component. The catheter 14 of Zacca is, at best, equivalent or similar to the catheter recited at lines 11-13 of applicants' claim 19 and in part (c) of applicants' claim 20. The proposed modification of Nash according to the teachings of Zacca inappropriately equates different structures and is clear error.

Applicants' independent claims 19 and 20 recite several structural relationships among components. A stationary liner surrounds the torque tube and extends from a sealing site in the housing longitudinally less than the axial length of the torque tube, terminating distally at an intersect area proximal to the distal end of the torque tube. A catheter having a proximal end terminating in the housing at an aspiration site extends distally to enclose the torque tube and liner, and the catheter extends distally beyond the intersect area, forming an aspiration lumen between the catheter and liner. The Examiner addresses the lack of prior art teaching of these structural relationships in the final rejection as follows:

The language "a catheter...extending distally to enclose the torque tube and the liner" in lines 11-12 of claim 19 and section (c) of claim 20 is a recitation of the relative position of two moveable components. Since the outer catheter (24) of the modified Nash apparatus is capable of being moved to a position where its distal end extends beyond the distal end modified liner (34) (sic) at an intersect area, it meets the claim requirements. *See*, final rejection, page 4.

Applicants strenuously disagree with this statement and submit that the fact that one physically *could* move the components of Nash into a position that would meet applicants' claimed structure is insufficient to meet the Examiner's burden of making a *prima facie* showing of obviousness. First, positioning the guide catheter (24) of Nash distally to enclose the catheter jacket (34) and torque tube as the Examiner proposes would destroy, or completely alter, the aspiration site and the path of the infusate, blood and debris. It would significantly alter and perhaps destroy the flow rate dynamics so heavily relied upon by Nash to evacuate debris from the site. The Examiner has provided no rationale that supports moving the outer catheter (24) of a modified Nash apparatus to a position in which it would meet applicants' claim recitations and applicants can conceive no reasonable rationale for repositioning the components of Nash as proposed.

The required obviousness rationales essentially pose the question of whether one skilled in the art would be motivated to make a combination of prior art elements in a predictable way that he or she would expect to work for its intended purpose. If so, the invention is obvious; if not, the invention is nonobvious. MPEP §2143 and the USPTO's KSR Guidelines (2007) and 2010 KSR Guidelines Update. Furthermore, in determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences *themselves* would have been obvious, but whether *the claimed invention as a whole* would have been obvious. If all of the claimed elements are known in the prior art, it may be important to identify what would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. If no such rationale exists, then one cannot conclude that the claim would have been obvious to one of ordinary skill in the art (See, MPEP § 2143, including citations to KSR).

Applicants respectfully submit that in finally rejecting the claims over a combination of Nash and Zacca, the Examiner is employing the same mis-interpretation of the teachings of Zacca that was employed at least in the rejection of the claims under 35 U.S.C. §103(a) over Zacca and Mische made in final Office Action mailed on February 4, 2010 that the applicants successfully overcame in the Appeal Brief submitted on August 4, 2010. Applicants submit, furthermore, for the reasons stated above, that the final rejection contains clear errors and that the Examiner has failed to make a *prima facie* showing of obviousness. The combination of Nash and Zacca fails to teach devices having the structural features, relationships and advantages of applicants' aspiration catheters as recited in pending claims 19 and 20. Applicants respectfully submit that pending claims 19 and 20 are in condition for allowance.

Respectfully submitted,


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October 27, 2011

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